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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,440	09/19/2003	Timothy John Henkel	9404.0005-02	8311

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,440

Applicant(s)

HENKEL, TIMOTHY JOHN

Examiner

Micah-Paul Young

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 12/8/05.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,4-8,11-26,34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by File et al (*Gemifloxacin versus amoxicillin/clavulanate in the treatment of acute exacerbation of chronic bronchitis. The 070 Clinical Study group*. J. Chemotherapy; August 2000; 12(4): 314-25). The claims are drawn to a method of reducing the recurrence of acute exacerbation of chronic bronchitis (AECB) in a patient in need thereof with an effective dosage of gemifloxacin.
3. The reference discloses a study where gemifloxacin is compared to amoxicillin/clavulanate in its treatment of AECB (abstract). The patients participating in the study have been suffering from chronic bronchitis for more two (2) consecutive years, and most days in a period of three (3) months (pg. 315). Gemifloxacin is given orally at 320 mg once daily for five (5) days (pg. 316). Patients were assessed at a follow-up where symptoms and bacterial activity were monitored and recorded (pg 316). The results of the study show that gemifloxacin is just as effective a treatment regimen for AECD as amoxicillin/clavulanate (pg. 323). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2,3,9,10,27-33, and 36-42 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of File et al (*Gemifloxacin versus amoxicillin/clavulanate in the treatment of acute exacerbation of chronic bronchitis. The 070 Clinical Study group. J. Chemotherapy*; August 2000; 12(4): 314-25) and Kim et al (WO 98/42705). The claims are drawn to a method of reducing the occurrences of AECB by administering gemifloxacin salts.

7. As discussed above the File study discloses a treatment for the reduction of AECB occurrences by administering gemifloxacin. However the study is silent to the particular salts of the drug available for use. Kim however discloses these compounds and suggests their use in the treatment of respiratory infections (abstract). The reference discloses various derivatives and salts including mesylate and sesquihydrate salts (pg 10, lin. 6- pg 11 lin 3). It is well within the level of skill in the art to substitute salts of known compounds into varying treatment regimens,

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in order to account for difference is solubility or other treatment variables. These substitutions would be obvious to one of ordinary skill in the art.

8. Regarding claims drawn to the specific follow-up regimen it is the position of the Examiner that such limitations do not impart patentability on the claims. The File study teaches that a long-term follow-up procedure is best for monitoring patients, however the specific intervals would be well within the level of skill in the art. Barring a showing of unexpected results regarding the particular follow-up procedures, it is the position of the Examiner that these limitations do not impart patentability.

9. With these things in mind, one of ordinary skill in the art would have been motivated to substitute the salts of Kim into the treatment regimen taught by File in order to account for changes in solubility during the treatment regimen. The artisan of ordinary skill would have been able to make these substitutions with an expected result of a method of reducing AECB occurrences in patients in need thereof.

Response to Arguments

10. Applicant's arguments filed 12/8/05 have been fully considered but they are not persuasive. Applicant argues that:

a. The File reference was not publicly available as prior art since the National Institute for Health library did not stamp the article into its collection until November of 2000.

11. Regarding this argument, it remains the position of the Examiner that even though the NIH library did not stamp the article as received until November of 2000, the article was available online and with other libraries around the country as of August 2000. The publication

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of the article online via services such as PUBMED and MEDLINE would provide ample public disclosure of the article and the teachings contained therein. Unless conclusive evidence can be provided that the publisher of the article actively withheld the volume 12 issue of the Journal of Chemotherapy, there is no evidence to support that the article was not available until November of 2000. With this in mind the claims remain rejected of over the sighted prior art. The file reference teaches the use of gemifloxacin in the treatment of AECSB, anticipating the instant claims.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

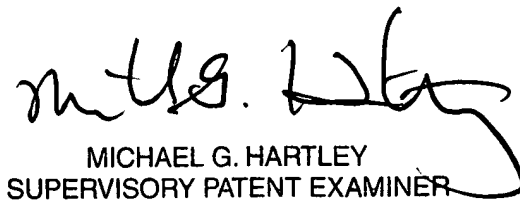
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER